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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,555	07/25/2003	Martin S. Linsell	P-154-US1	3562
27038	7590	09/12/2007		
THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080			EXAMINER KUMAR, SHAILENDRA	
			ART UNIT	PAPER NUMBER
			1621	
			MAIL DATE	DELIVERY MODE
			09/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/627,555

Applicant(s)

LINSELL ET AL.

Examiner

SHAILENDRA -. KUMAR

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15-17, 20-26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 28-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 20-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/29/07</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

This office action is in response to applicants' communication filed on 6/29/07.

Claims 1-11, 15-17, 20-26, and 28-34 are pending in this application. Claims 12-14, 18-19 and 35-40 have been canceled.

Claims 15-17 and 28-34 have been withdrawn from the consideration, being drawn to the non elected invention.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 6/29/07 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner.

Obvious type double patenting rejections are hereby withdrawn subsequent to applicants' filing of acceptable Terminal Disclaimer. The examiner has noted the filing of Terminal disclaimer against 11/654,117, and the same has been entered and accepted.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-11 and 20-26 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Moran et al, all for the reasons of record.

Claims 1-7 are directed to a crystalline compound and Claims 8-11 are directed to pharmaceutical compositions comprising the crystalline compound. In particular, Claim 1 recites "crystalline N-{2-[4-((R)-2-hydroxy-2-phenylethylamino)phenyl]ethyl)-(R)-2-hydroxy-2-(3-formamido-4-hydroxyphenyl)ethylamine dihydrochloride".

Applicants' arguments were fully considered and were not found convincing. Applicants point out to the MPEP that as required by M.P.E.P. §2143, to establish a *prima facie* case of obviousness, the Examiner must at least show (1) that the prior art reference teaches or suggests all the claim limitations, (2) that there is some suggestion or motivation, either in the reference or in the knowledge available to one of ordinary skill in the art, to modify the reference, and (3) that there is a reasonable expectation of success.

Examiner would like to point out to the 1st point, and the 2nd point, the prior art expressly suggests hydrochloride salt, see column 19, line 44-45. With respect to third point, inasmuch as hydrochloride salt is described, there is reasonable expectation of

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success of achieving dihydrochloride salt also, especially in view of two nitrogen atoms being there.

Applicants point out that there is list of possible salt in the reference and such a list is a merely a disclosure in the reference. The examiner does not dispute that the reference discloses list of possible salt, but hydrochloride salt is such a common salt, and that is the 1st salt mentioned in the reference, the choice becomes automatic. Applicants are not claiming some uncommon salt used in the pharmaceutical art, and therefor there is express suggestion in the art to select hydrochloride salt. Same explanation goes with the dihydrochloride salt. Dihydrochloride salt is obvious over mono hydrochloride salt, especially in view of the available amino nitrogens in the compound.

Applicants point out that since reference does not teach dihydrochloride salt, thus it cannot teach that the salt is crystalline. The examiner would like to point out that hydrochloride salt of the instant claimed compound can be crystalline only, absent evidence to the contrary. The physical characteristic is inherent to the compound, absent evidence to the contrary. Also column 35, line 34, explicitly suggest that instant claimed compounds are indeed crystalline in nature.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

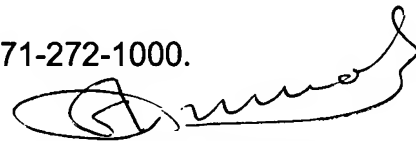
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SHAILENDRA - KUMAR
Primary Examiner
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S. Kumar
9/09/2007